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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,431	10/25/2001	Sean A. McCarthy	10147-6U2	5729

30405 7590 10/06/2004

MILLENNIUM PHARMACEUTICALS, INC.
40 Landsdowne Street
CAMBRIDGE, MA 02139

EXAMINER

NASHED, NASHAAT T

ART UNIT PAPER NUMBER

1652

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/042,431	Applicant(s) MCCARTHY ET AL.	
	Examiner Nashaat T. Nashed, Ph. D.	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 52-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/22/04</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1652

The application has been amended as requested in the communication filed July 22, 2004. Accordingly, claims 52, 59, 66, and 71 have been amended.

Claims 52-75 are pending and under consideration.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 52-75 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth in the prior Office action mailed March 15, 2004.

Applicants argue that the examiner has not established a *prima facie* case of lack of utility because from reading the specification one of ordinary skill in the art would recognize the claimed invention has well established utility.

Applicants' arguments filed 7/22/04 have been fully considered, but they are found unpersuasive. The previous Office action sets out a *prima facie* case of lack of utility, explaining by sound scientific reasoning why a person of ordinary skill in the art would not be able to identify a specific or substantial utility after reading applicants' specification. Applicants have presented no evidence or, indeed, any convincing argument to establish that the claimed invention has a well-established utility, or specific or substantial utility. It is agreed that the polypeptide of SEQ ID NO: 47 is a possible lipase. As indicated in the previous Office action, lipases form a large family of enzyme each of which has a specific chemical and biological function. The application has disclosed neither the biological nor the chemical utility of the polypeptide of SEQ ID NO: 47. Applicants' response to the Office action mailed March 15, 2004 clearly indicate that the TANGO 294 polypeptide exhibit lipase or lipase-like activity. Lipase-like activity is not a specific or substantial utility and encompasses any esterase activity including any sterol hydrolase activity, peptidase, and phospholipase activity. The utility of the claimed method is not in the utility of the enzyme itself, but it is in the utility of the product of the method, i. e., the compound that binds and inhibits the activity of the polypeptide of SEQ ID NO: 47. Again, the specification provides neither specific nor substantial utility for a compound that binds and inhibits the polypeptide of SEQ ID NO: 47. Also, applicants provide appendix B, which shows that TANGO 294 is detected only in the stomach tissue. That is no support for specific or substantial utility for a compound that binds and inhibits the polypeptide of SEQ ID NO: 47. The specification has failed to provide any specific chemical function or possible role in a metabolic pathway. Thus, the claims remain rejected.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1652

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 52-75 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the compounds identified by the claimed method.

Claims 52-75 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth for lack of enablement in the previous Office action mailed March 15, 2004.

Applicants argue that the claimed method is fully enabled in the specification.

Applicants' arguments filed 7/22/04 have been fully considered but they are not deemed to be persuasive. Enablement requires a disclosure sufficient to allow a person of skill in the art to practice the full scope of the claimed invention without undue experimentation. The previous Office action sets out a *prima facie* case of non-enablement, explaining by sound scientific reasoning why a person of ordinary skill in the art would doubt that the guidance of the specification would enable practice of the full scope of the claimed invention without undue experimentation. Applicants have presented no evidence or, indeed, any arguments to establish the adequacy of the disclosure to enable the scope of the instant claims. Applicants merely assert that identifying a polypeptide having 90% sequence identity to SEQ ID NO: 47 or 49 and a substrate to assay the lipase activity would not constitute undue experimentation. Applicants make no effort to explain why they consider the disclosure of a human lipase with no identifiable chemical or biological function would be sufficient enablement for a method of identifying a compound that binds and inhibits some undefined lipase activity of the polypeptide of SEQ ID NO: 47 or 49. The enablement rejection here is not only for the scope of the structure and function of the polypeptide of SEQ ID NO: 47 and 49, but also for the use of the product of the claimed method. Conclusory statements unsupported by evidence or scientific reasoning are insufficient to overcome the *prima facie* case of non-enablement set out in the previous Office action.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1652

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nashaat T. Nashed, Ph. D.
Primary Examiner
Art Unit 1652